

REMARKS

A Request for Continued Examination (RCE) accompanies this Reply and Amendment.

Claims 1, 3, 7-12, 15-26, and 33 are pending and under consideration for purposes of the instant Office Action. Claims 2, 4-6, and 13-14 were previously canceled, and claims 27-33 were previously withdrawn.

Claim 1 has been further amended to more particularly recite the configuration of the claimed tablet according to the subject invention. Specifically, Claim 1 now recites that the claimed tablet has an inactive segment having top and bottom faces wherein only one of those faces comes into contact with the active segment(s), and each active segment also has a top and bottom face wherein only one of those faces contacts the inactive segment.

Applicants respectfully submit that the amendments are supported by the specification and that no new matter has been added. Support for the current amendments is found in the specification, e.g., in the drawings which illustrate the contacting faces (interfaces) of each segment, and the accompanying text describing the drawings at pages 21-24. Support is further provided at page 5, lines 11-14, and at page 19, line 31 continuing to page 20, line 5. Reconsideration of claims 1, 3, 7-12, 15-26, and 33, as amended, is respectfully requested in view of the further amendments to the claims submitted in this Reply.

Applicants thank the Examiner for the careful consideration of the previous amendments and accompanying remarks. Consideration by the Examiner of the Terminal Disclaimers submitted in the previous Reply, and the consequent withdrawal of the obviousness-type double patenting rejections, is gratefully acknowledged.

The obviousness rejections under 35 USC 103(a) remain. These rejections are discussed below in view of the newly amended claims:

*Rejections under 35 USC 103(a)*

Claims 1, 3, 7-12, 15-26, and 33 stand rejected as being unpatentable under 35 USC 103(a), citing Langauer (US Pat. No. 3,723,614), in view of Ting, et al. (WO 00/18447). Applicants respectfully traverse.

The Office Action identifies Langauer as describing a scored tablet for accurate breaking and administration of the active from the separate tablet portions. However, the Office Action further admits that Langauer fails to describe a tablet having a segment containing either an undetectable amount of drug or a pharmacologically ineffective amount of drug (i.e., an *inactive* segment).

The Office Action then cites the reference of Ting, and asserts that it would have been obvious to make a scored tablet of Langauer and combine it with a tablet having two immediate release compartments substantially enveloped by a scored extended release compartment, as described by Ting, to produce the instant invention. Applicants disagree, since combining Langauer and Ting would only provide scored tablets of Langauer (as the active portions) enveloped by a scored extended release composition (the inactive portion).

The subject invention is different than this “combination” resulting from Langauer and Ting. The simple concept of a bi-layer tablet, as claimed, is not taught or suggested by either reference, nor is the claimed tablet taught or suggested by the references taken in combination. Applicants note that the claims, as currently amended, clarify the distinctions between the subject invention and a Langauer/Ting combination by expressly reciting that the inactive segment has a top and bottom face wherein only one of those faces comes into contact with the active segment(s). Moreover, each active segment also has a top and bottom face wherein only one of those faces contacts the inactive segment.

By contrast, the combination of the Langauer and Ting references describes active core tablets substantially enveloped by an inactive coating layer. Therefore, a Langauer/Ting combination would result in active tablets having more than one face contacting the inactive portion of the tablet, and the inactive portion would have more than one face contacting the active core tablets.

In addition, the active layer of a tablet according to the subject invention is scored to advantageously form substantially identical first and second unitary segments. The active portions of a Langauer/Ting combination tablet are not formed from a “scored” layer; rather, the active portions of a Langauer/Ting tablet are discrete tablets formed individually and then “substantially enveloped” by the inactive composition. Applicants therefore

respectfully submit that the subject invention, as now claimed, is not provided by the combination of Langauer and Ting.

Advantageously, the subject tablets, including the formation of three or more segments from only two layers (one layer forming the inactive segment and one divided layer forming two active segments), can be achieved using a conventional bi-layer tablet press using a single compression step. Langauer and Ting, either individually or combined, form the two active portions in two separate compression steps, and require a third compression step to form the inactive “envelope.”

Not only would a Langauer/Ting combination tablet require at least two, and preferably three, compression steps as discussed above, but the press-coating envelopment step can further require specialized press-coating machinery or tooling. Such required machinery or tooling can advantageously be avoided by use of the conventional bi-layer or tri-layer tablet press process employed in the manufacture of the subject invention. .

Applicants respectfully submit that the limitation now expressly recited within the claims of an inactive segment having top and bottom faces wherein only one of those faces comes into contact with the active segment(s), and each active segment also has a top and bottom face wherein only one of those faces contacts the inactive segment necessarily excludes the substantial enveloping by “a scored film coating” as taught by Ting (see final paragraph at page 5 of the instant Office Action). The envelopment step used in Ting requires the core active tablets to have at least two faces in contact with the inactive portion, and further requires more than one face of the inactive portion to contact the active core tablets.

Neither Langauer nor Ting et al. references teach or suggest a readily divisible tablet which has an inactive layer/segment which contacts only one face of each active layer/segment and an active layer/segment which contacts only one face of the inactive layer/segment. Langauer, as admitted in the Office Action, does not describe an inactive segment.

The Office Action, at pages 6 through 11, then goes on to present rejections of certain claims based on the combination of Langauer and Ting, provides rebuttal to the applicants' previous arguments and concludes that the arguments were not persuasive. Specifically

addressed are Claims 1, 3, and 7-9, Claims 3, 10, 11, 12, 15 and 16, alone, and the claim sets of Claims 17 and 33, Claims 21-22, and Claims 23-26. The rejection of Claim 1 is addressed above and reconsideration is requested in view of the current amendments. The other rejections are directed to claims that depend from, and therefore incorporate the limitations of, Claim 1. The applicants' position for non-obviousness of Claim 1 applies to these dependent claims as well.

Further, there is no motivation provided in the prior art to modify the dosage forms described in Langauer or Ting et al. which would lead a person of ordinary skill in the art to the unique and unobvious tablets of the claimed invention. Accordingly, applicants believe the claimed invention is unobvious in view of Langauer or Ting taken separately or combined. In view of the above amendments to the claims, and the accompanying remarks, withdrawal of all the rejection under 35 USC 103(a), citing Langauer in view of Ting et al., is therefore respectfully requested upon reconsideration.

Claims 17-18 are rejected as being unpatentable under 35 USC 103(a), citing Langauer in view of Ting, et al., and further in view of Addicks, et al. (US 5,041,430). The rejection reiterates the rationale behind the citation of Langauer and Ting, and uses Addicks for its disclosure of employing warfarin in the tablet.

Applicants' position, as discussed above, regarding the failure of Langauer or Ting, separately and together, to make obvious the claimed invention is incorporated herein by reference. Addicks does not cure the defects of Langauer or Ting irrespective of the use of a particular drug in the claimed invention, including warfarin.

Addicks, even taken in combination with Langauer and/or Ting, does not teach or describe a tablet as claimed – namely, a tablet comprising an inactive segment having only one face which contacts an active segment and having only one face of the active segment contacting the inactive segment – i.e., the active is not enveloped or even substantially enveloped by the inactive. Combining Addicks with the Langauer and/or Ting references would only provide a teaching of two warfarin-containing tablets substantially enveloped by an inactive composition, which is not the claimed invention.

Claims 17 and 19 are rejected as being unpatentable under 35 USC 103(a), citing Langauer in view of Ting, et al., and further in view of Eberlin, et al. (US 3,696,091). This rejection uses Eberlin for its disclosure of employing digoxin in the tablet. Applicants' respectfully submit that Eberlin does not cure the defects of Langauer or Ting. Combining Eberlin with the Langauer and/or Ting references would only provide a teaching of two digoxin-containing tablets substantially enveloped by an inactive composition. Eberlin does not teach or describe a tablet having a first inactive segment having only one face which contacts an active layer and having only one face of the active segments which contacts the inactive segment – i.e., the active is not “substantially enveloped” by the inactive.

Claims 17 and 20 are rejected as being unpatentable under 35 USC 103(a), citing Langauer in view of Ting, et al., and further in view of Franz, et al. (US 6,555,581). The rejection again reiterates the rationale behind the citation of Langauer and Ting, and uses Franz for its disclosure of employing levothyroxin in the tablet.

Applicants' position, as discussed above, regarding the failure of Langauer or Ting, separately and together, to make obvious the claimed invention is incorporated herein by reference. The Franz reference does not cure the defects of Langauer or Ting. Combining Franz with the Langauer and/or Ting references would only provide a teaching of two levothyroxin-containing tablets substantially enveloped by an inactive composition. Franz does not teach or describe a tablet having a first inactive segment, only one face of which contacts an active layer and having only face of the active segment contacting the inactive segment – i.e., the active is not “substantially enveloped” by the inactive.

In view of these defects of Langauer and Ting, even if combined with any one of Addicks, Eberlin, or Franz, applicant submits that the claimed invention would not have been obvious in view of these references. This tablet configuration arrived at by combining the secondary references with Langauer and/or Ting, et al., is not the claimed invention. Reconsideration and withdrawal of the obviousness rejections citing Langauer and Ting, combined with any one of Addicks, Eberlin, or Franz, is respectfully urged.

Applicants believe the subject claims, as amended, are now in condition for allowance, and respectfully request that a Notice of Allowance be issued for the instant application.

Should further information or clarification be required on any of these matters, applicants invite the Examiner to contact the undersigned at the address or phone/fax number provided below.

Respectfully submitted,

Dated: 20 April 2011

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